what else should I report?
Alongside reporting side effects, the Yellow Card Scheme can be used to report any effects from switching between different versions of an AED, such as breakthrough seizures or more frequent seizures.

For some AEDs there are several different versions of the same drug available. This might include a branded drug (the original version of the drug) and other generic versions (with the same active ingredient as the original version). Different versions might be different in size, shape or colour, but they all have the same active ingredient (the chemical part of a drug that works in the body to control or treat a condition or disease). Although all versions of a drug have to have the same amount of active ingredient to the original version, there can be differences in some of the other ingredients (such as colours and binding agents). For some people these changes might affect how well the drug works to control seizures.

why should I report this?
The MHRA is collecting evidence about whether switching between different versions of AEDs can affect seizures. By reporting any changes in your seizures through the Yellow Card Scheme, you are helping to show the impact of switching AEDs. This will help the MHRA to understand the risks around switching AEDs, and inform what guidance they give to healthcare professionals (including specialists, GPs and pharmacists) about prescribing and dispensing AEDs.

Visit our website for more on the MHRA guidance for prescribing anti-epileptic drugs.
**drug development and side effects**

When new drugs are developed, part of the process is ‘clinical trials’ to test the drug for safety (that it doesn’t cause illness), effectiveness (how well it works for the condition it is designed to treat) and whether it causes any common or predictable side effects.

During development, drugs are tested on people. Firstly they are tested on healthy volunteers (without the disease or condition the drug is being developed for) to give information about how the drug distributes in the body, and the likely doses needed. They are then tested in people with the relevant disease or condition to test their effectiveness on that disease or condition. Some groups of people are not included in these trials: children, people aged 60 or over, and pregnant women, so the effect in these groups is not known at this stage.

Any side effects seen are recorded during these trials. Once licensed, drugs can be prescribed and used.

Visit www.epilepsysociety.org.uk/aeddevelopment for more about how drugs are developed.

** Aren’t all side effects of a drug already known?**

Any side effects that become known when drugs are developed are recorded, and listed in the patient information leaflet that comes with every prescription of medicines. These side effects are listed according to how often they happen (how many people are likely to experience the side effect).

They are listed as:
- very common – affects at least 1 in 10 people;
- common – affects 1 in 100 to 1 in 10 people;
- occasional – affects 1 in 1,000 to 1 in 100 people;
- rare – affects less than 1 in 1,000 people;
- very rare – affects less than 1 in 10,000 people; and
- extremely rare – affects less than 1 in 100,000 people.

Some side effects only become known after a drug is used in the population (after it is licensed and starts to get prescribed). This might be because the side effects only happen after a drug is used for a long time (long-term or ‘chronic’ side effects), or they become known after a greater number of people have started to use the drug. Also, some side effects are ‘idosyncratic’ (unique to the person experiencing them) and so cannot be predicted.

**more about the yellow card scheme**

**How do I get a Yellow Card?**

You can get a Yellow Card from your GP surgery, pharmacist, hospital or NHS drop-in centre, or by calling the yellow card hotline on 0808 100 3352. You can also download the form, or complete it online, at www.yellowcard.mhra.gov.uk

**What information will I need to include?**

When you report a side effect, you will be asked for the following information:

- your name;
- your contact details (address, email or phone number);
- your age, gender, height, weight and ethnicity;
- the name and batch number of the medicine (found on the packaging);
- when you started and stopped the medicine (if appropriate);
- how much you take;
- where you got the medication from;
- what you did as a result of the side effect (such as stopped or reduced the dose);
- details of the side effect you experienced, for how long and how it affected you (you will have room to explain your answer); and
- whether you have reported the side effect to anyone (such as your doctor or pharmacist).

**What happens once I report it?**

The doctors, pharmacists and scientists at the MHRA look into each Yellow Card report. They compare it with other information on the medicine (from the development trials) to check if it is a previously unknown side effect, and consider how it affects the safety of the medicine. They might also be able to issue relevant warnings and safety advice about taking the medicine.

The MHRA is also looking at data around reporting of breakthrough seizures to see how this might affect the way AEDs are prescribed and dispensed.

**further information**

www.yellowcard.mhra.gov.uk – information from the MHRA on the Yellow Card Scheme.